

CLOVE HILL ACNE SAFE MINERAL SUNSCREEN SPF 40- zinc oxide cream
Clove Hill LLC

DRUG FACTS

ACTIVE INGREDIENTS:

Zinc Oxide 20%

PURPOSE:

Sunscreen

USES:

Helps prevent sunburn. If used as directed with other sun protection measures (see directions), decreases the risk of skin cancer and early skin aging caused by the sun.

WARNINGS:

For external use only. Do not use on damaged or broken skin. Stop use and ask a doctor if rash occurs. When using this product, keep out of eyes. Rinse with water to remove.

Keep out of the reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

DIRECTIONS:

Apply liberally 15 minutes before sun exposure.

Reapply: After 40 minutes of swimming or sweating

Immediately after towel drying • At least every 2 hours

Children under 6 months: Ask a doctor

SUN PROTECTION MEASURES:

Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including:

- Limit time in the sun, especially from 10:00 a.m.-2:00 p.m.
- Wear long-sleeved shirts, pants, hats, and sunglasses

INACTIVE INGREDIENTS:

C12-15 Alkyl Benzoate, Caprylhydroxamic Acid, Caprylyl Glycol, Cetyl PEG/PPG10/1 Dimethicone, Cyclohexasiloxane, Cyclopentasiloxane, Dimethicone, Dimethicone Crosspolymer, Dimethicone/Vinyl Dimethicone Crosspolymer, Dimethiconol, Disodium EDTA, Glycerin, Hydrogen Dimethicone, Microcrystalline Wax, PEG-10 Dimethicone, PEG-30 Dipolyhydroxystearate, Polyglyceryl-4 Isostearate, Polyhydroxystearic Acid, Polysorbate 20, Sodium Chloride, Stearyl Dimethicone, Tetrahexyldecyl Ascorbate, Tocopheryl Acetate, Triethanolamine, Triethoxycaprylylsilane, Water

OTHER INFORMATION:

Protect this product from excessive heat and direct sun

May stain some fabrics

Principal Display Panel - 115 g Bottle Label

CLOVE HILL

come home to clear skin

acne-safe

mineral sunscreen

spf 40 broad spectrum

water resistant (40 mins)

net wt. 4 oz /115 g

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Manufactured For: Clove Hill, Wheat Ridge CO 80033

CLOVE HILL
 come home to clear skin



acne-safe
 mineral sunscreen

spf 40 broad spectrum
 water resistant (40 mins)

net wt. 4 oz / 115 g

CLOVE HILL ACNE SAFE MINERAL SUNSCREEN SPF 40

zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82746-205
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	200 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 5) (UNII: 035JKJ76MT)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	

CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)
DIMETHICONE 100 (UNII: RO266O364U)
DIMETHICONE CROSSPOLYMER (450000 MPA.S AT 12% IN CYCLOPENTASILOXANE) (UNII: UF7620L1W6)
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)
DIMETHICONOL (2000 CST) (UNII: T74O12AN6Y)
EDETATE DISODIUM (UNII: 7FLD91C86K)
GLYCERIN (UNII: PDC6A3C0OX)
HYDROGEN DIMETHICONE (20 CST) (UNII: 12Z59IF64N)
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)
PEG-30 DIPOLYHYDROXYSTEARATE (4000 MW) (UNII: 9713Q0S7FO)
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)
POLYSORBATE 20 (UNII: 7T1F30V5YH)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
STEARYL DIMETHICONE (400 MPA.S AT 50C) (UNII: R327X197HY)
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
TROLAMINE (UNII: 9O3K93S3TK)
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)
WATER (UNII: 059QF0KO0R)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82746-205-04	115 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	07/01/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	07/01/2022	

Labeler - Clove Hill LLC (071183319)

Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	ANALYSIS(82746-205)

Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing Inc. (FMI)		793406000	MANUFACTURE(82746-205) , PACK(82746-205)